

SEP 28 2005

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 14-R-0162  
CUSTOMER NUMBER: 17008

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Nucryst Pharmaceuticals  
50 Audubon Rd  
Suite B  
Wakefield, MA 01880

Telephone: (781)-246-6044

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report )	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs	0	53	17	10	80
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGN

APHIS

SIGNED

Sept. 05

(b)(6), (b)(7)(c)

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 14-R-0162
2. Number 80 of animals used in this study.
3. Species (common name) Guinea Pig of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Please see attached letter.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)
6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ CFR \_\_\_\_\_

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(b)(6), (b)(7)c

21 September 2005

Elizabeth Goldentyer, DVM  
Regional Director, Animal Care  
USDA-APHIS Eastern Regional Office  
920 Main Campus Drive  
Suite 200, Unit 3040  
Raleigh, NC 27606-5210  
Ph. 919-716-5532

Subject: Annual Report of Research Facility for 1 Oct 2004 through 30 Sept 2005  
USDA Registration # 14-R-0162

Dear Dr. Goldentyer:

Enclosed please find our annual statistical report (APHIS Form 7023) pertaining to research activities at NUCRYST Pharmaceuticals, Inc. The use of covered animal species reported in USDA Category E (animal pain &/or distress without alleviation) is explained in the following section.

Guinea pigs were used to test the anti-inflammatory activity of nanocrystalline silver creams in a model of allergic contact dermatitis. Dermatitis was induced on guinea pig skin using dinitro-chlorobenzene (DNCB) in a 2-stage application. Once skin lesions appeared, the animals were treated with test compounds including placebo creams. Most of the animals were treated with different test compounds including known anti-inflammatory compounds that reduced the intensity &/or duration of the dermatitis. Some animals were left untreated to serve as negative controls. After five days of treatment all animals were euthanized and skin biopsies were collected for histology and histochemistry.

The model employed a detailed lesion scoring system that was used daily to assess lesion severity and response to treatment. In addition, guinea pig body weight and overall health parameters were monitored daily for the duration of the study. Based on these parameters, the induced dermatitis did not cause significant pain or distress in the majority of animals that were used. Guinea pigs that had lesions with a score greater than 4+ for a period of more than 48 hours were categorized in USDA Category E. During the reporting period, we used a total of 80 guinea pigs. Of this total, 10 were categorized in USDA Category E.

Guinea pigs were selected for this study because the allergic contact dermatitis model in guinea pig is well characterized and dermatitis in this model is present for an appropriate duration for evaluating the activity of test compounds. The histological findings in guinea

pig allergic contact dermatitis are very similar to the eczematous changes in human allergic contact dermatitis.

Please contact me at 781-246-6044 if you require any additional explanation regarding our USDA annual report.

Sincerely,

(b)(6), (b)(7)c

NUCRYST Pharmaceuticals, Inc.